



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

JUL - 8 1997

Stephen G. Kunin  
Deputy Assistant Commissioner for  
Patent Policy and Projects  
U.S. Patent and Trademark Office  
Box Pat. Ext.  
Assistant Commissioner for Patents  
Washington, D.C. 20231

Re: NASCOBAL™  
Docket No. 97E-0076

RECEIVED

JUL 16 1997

PATENT EXTENSION  
A/C PATENTS

Dear Mr. Kunin:

This is in regard to the application for patent term extension for U.S. Patent No. 4,724,231 filed by Nastech Pharmaceutical Company, Inc. under 35 U.S.C. § 156. The human drug product claimed by the patent is NASCOBAL™ (cyanocobalamin), which was assigned New Drug Application (NDA) No. 19-722.

A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that it **does not** represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1), and interpreted by the courts in Glaxo Operations UK Ltd. v. Quigg, 706 F. Supp. 1224 (E.D. Va. 1989), aff'd, 894 F. 2d 392 (Fed. Cir. 1990). For example, BETALIN 12, CORBAVITE, CYANOCOBALAMIN, RUBRAMIN, RUVITE, and VIBISONE contain the same active ingredient as in NASCOBAL™, cyanocobalamin (see attachment).

The NDA was approved on November 5, 1996, which makes the submission of the patent term extension application on January 3, 1997, timely within the meaning of 35 U.S.C. § 156(d)(1).

Should you conclude that the subject patent is eligible for patent term extension, please advise us accordingly. As required by 35 U.S.C. § 156(d)(2)(A) we will then determine the applicable regulatory review period, publish the determination in the Federal Register, and notify you of our determination.

Please let me know if we can be of further assistance.

Sincerely,



Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs

**Attachment**

cc: Gerald T. Bodner, Esq.  
Hoffman & Baron  
350 Jerico Turnpike  
Jerico, NY 11753

# **APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS**

The products in this list have been approved under sections 505 and 507 of the Federal Food, Drug, and Cosmetic Act. This volume and accompanying first supplement are current through January 31, 1997.

## **17<sup>TH</sup> EDITION**



**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
PUBLIC HEALTH SERVICE  
FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF MANAGEMENT  
DIVISION OF DATABASE MANAGEMENT**

**1997**

## PRESCRIPTION DRUG PRODUCT LIST

3-85

<u>COSYNTROPIN</u>	INJECTABLE; INJECTION CORTROSYN + ORGANON	0 .25MG/VIAL	N16750 001	CREAM; TOPICAL EURAX + WESTWOOD SQUIBB	10%	N06927 001
<u>CROMOLYN SODIUM</u>	AEROSOL, METERED; INHALATION INTAL + FISONS	0 .8MG/INH	N18887 001 DEC 05, 1985	LOTION; TOPICAL <u>CROTAN</u> <u>GALDERMA</u> <u>EURAX</u> + WESTWOOD SQUIBB	<u>10%</u>	N87204 001 N09112 003
CAPSULE; INHALATION INTAL + FISONS	20MG	N16990 001	N19188 001 DEC 22, 1989	INJECTABLE; INJECTION CUPRIC CHLORIDE IN PLASTIC CONTAINER + ABBOTT	EQ 0 .4MG COPPER/ML	N18960 001 JUN 26, 1986
CAPSULE; ORAL GASTROCROM + MEDEVA	100MG	N20479 001 FEB 29, 1996	N19722 001 NOV 05, 1996	GEL, METERED; NASAL NASCOBAL + NASTECH	0 .5MG/INH	
CONCENTRATE; ORAL GASTROCROM + MEDEVA	100MG/5ML			INJECTABLE; INJECTION <u>CYANOCOBALAMIN</u> <u>COBAVITE</u> STERIS	<u>0 .1MG/ML</u> <u>1MG/ML</u>	
SOLUTION; INHALATION <u>CROMOLYN SODIUM</u>	<u>10MG/ML</u>	N74209 001 APR 26, 1994	N18596 001 MAY 28, 1982	<u>CYANOCOBALAMIN</u> <u>ELKINS SINN</u> FUJISAWA HOECHST MARION RSSL LUITPOLD SOLOPAK	<u>0 .1MG/ML</u> <u>1MG/ML</u> <u>0 .1MG/ML</u> <u>1MG/ML</u> <u>1MG/ML</u>	N83013 001 N83064 001 N80515 002 N80557 002 N80564 001 N80737 001 N87551 001 FEB 29, 1984
<u>AN</u>	<u>INTAL</u> + FISONS	<u>10MG/ML</u>	N74443 001 JAN 30, 1995	STERIS	<u>0 .1MG/ML</u> <u>1MG/ML</u>	N80573 002 N83120 001 N80573 001 N83120 002 N80554 001 N80554 002
SOLUTION/DROPS; OPHTHALMIC CROLOM + BAUSCH AND LOMB	4%	N18306 001 MAR 18, 1983	WYETH AYERST	RUBRAMIN PC + SQUIBB ROVITE SAVAGE LABS	<u>1MG/ML</u> <u>0 .1MG/ML</u> <u>1MG/ML</u> <u>1MG/ML</u>	NO6799 004 N80570 002
SPRAY, METERED; NASAL NASALCROM + FISONS	5 .2MG/SPRAY					

PREScription DRUG PRODUCT LIST

3-86

<u>CYANOCOBALAMIN</u>						
<u>INJECTABLE; INJECTION</u>						
<u>AP</u>	<u>VIBISONE</u>	<u>1MG/ML</u>				
	<u>FUJISAWA</u>					
TABLET; ORAL						
CYANOCOBALAMIN	1MG					
+ WEST WARD						
<u>CYANOCOBALAMIN;</u>	<u>*MULTIPLE*</u>					
SEE <u>ASCORBIC ACID</u> ; <u>BIOTIN</u> ; <u>CYANOCOBALAMIN</u> ; <u>DEXPANTHENOL</u> ;						
<u>ERGOCALCIFEROL</u> ; <u>FOLIC ACID</u> ; <u>NIACINAMIDE</u> ; <u>PYRIDOXINE</u>						
<u>HYDROCHLORIDE</u> ; <u>RIBOFLAVIN PHOSPHATE SODIUM</u> ; <u>THIAMINE</u>						
SEE <u>ASCORBIC ACID</u> ; <u>BIOTIN</u> ; <u>CYANOCOBALAMIN</u> ; <u>ERGOCALCIFEROL</u> ;						
<u>FOLIC ACID</u> ; <u>NIACINAMIDE</u> ; <u>PANTOTHENIC ACID</u> ; <u>PHYTONADIONE</u> ;						
<u>PYRIDOXINE</u> ; <u>RIBOFLAVIN</u> ; <u>THIAMINE</u> ; <u>VITAMIN A PALMITATE</u> ;						
<u>VITAMIN E</u>						
SEE <u>COBALT CHLORIDE</u> , <u>CO-57</u> ; <u>CYANOCOBALAMIN</u> ; <u>CYANOCOBALAMIN</u> ,						
<u>CO-57</u> ; <u>INTRINSIC FACTOR</u>						
<u>CYANOCOBALAMIN</u> ; <u>CYANOCOBALAMIN</u> , <u>CO-57</u> ; <u>CYANOCOBALAMIN</u> , <u>CO-58</u>						
N/A; N/A						
DICOPAC KIT						
AMERSHAM	N/A; N/A; N/A					
	N17406 001					
<u>CYANOCOBALAMIN</u> ; <u>CYANOCOBALAMIN</u> , <u>CO-57</u> ; <u>INTRINSIC FACTOR</u>						
N/A; N/A						
CYANOCOBALAMIN CO 57 SCHILLING TEST KIT						
MALLINCKRODT	0.1MG; 0.5 uCi; 60MG					
	N16635 001					
<u>CYANOCOBALAMIN</u> , <u>CO-57</u>						
CAPSULE; ORAL						
RUBRATOPE-57						
BRACCO	0.5-1 uCi					
<u>CYANOCOBALAMIN</u> , <u>CO-57</u> ; <u>*MULTIPLE*</u>						
SEE <u>COBALT CHLORIDE</u> , <u>CO-57</u> ; <u>CYANOCOBALAMIN</u> ; <u>CYANOCOBALAMIN</u> ,						
<u>CO-57</u> ; <u>INTRINSIC FACTOR</u>						
SEE <u>CYANOCOBALAMIN</u> ; <u>CYANOCOBALAMIN</u> , <u>CO-57</u> ; <u>CYANOCOBALAMIN</u> ,						
<u>CO-58</u>						
SEE <u>CYANOCOBALAMIN</u> ; <u>CYANOCOBALAMIN</u> , <u>CO-57</u> ; <u>INTRINSIC FACTOR</u>						
<u>CYCLACILIN</u>						
N80557 003						
TABLET; ORAL						
CYCLACILIN						
N84264 001						
+ TEVA						
	250MG					
	+					
	500MG					
<u>CYCLOBENZAPRINE HYDROCHLORIDE</u>						
N73541 001						
MAY 23, 1995						
N71611 001						
MAY 03, 1989						
N72854 001						
NOV 19, 1991						
N73683 001						
FEB 26, 1993						
N73144 001						
MAY 31, 1991						
N74436 001						
NOV 30, 1994						
N74421 001						
SEP 29, 1995						
N73143 001						
NOV 27, 1991						
<u>CYCLOPENTOLATE HYDROCHLORIDE</u>						
N16089 002						
SOLUTION/DROPS; OPHTHALMIC						
<u>AK-PENTOLATE</u>						
AT						
AKORN						
<u>CYLOGYL</u>						
AT						
+ ALCON						
AT						
+						
<u>0.5%</u>						
<u>1%</u>						
<u>2%</u>						
N85555 001						
N84109 001						
N84110 001						
N84108 001						